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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,315	08/19/2003	John Spiridigliozzi	760-100 CIP	3552

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,315

Applicant(s)

SPIRIDIGLIOZZI ET AL. C

Examiner

Christopher D. Prone

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
4a) Of the above claim(s) 16, 18, 34, 36 and 38-47 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-15, 17, 19-33, 35 and 37 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/30/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15, 17, 19-33, 35, and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5-17 of copending Application No. 10/166,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite all the same structural requirements.

In regards to claims 1-15 and 17, Independent claim 1 recites that the implant comprises a first tubular layer of ePTFE and a second tubular layer of a textile material, these layers correspond to the first and third layers of claim 1 in copending Application No. 10/166,842. This claim is broader than the claim of copending Application No.

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10/166,842 but it still contains the same structural limitations.

In regards to claims 19-33, 35, and 37, these claims clearly recite all the same structural limitations as claims 1-3 and 5-17 of copending Application No. 10/166,842.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15, 17, 19-33, 35, and 37 rejected under 35 U.S.C. 103(a) as being unpatentable over Planck (4,850,999) in view of Banas (USPN 6,264,684), and further in view of Pinchuk (USPN 5,628,788).

With reference Figure 1 Planck discloses a composite multilayer implantable structure comprising two discrete layers: a first inner tubular layer 12' and a second outer tubular layer 12'' formed of ePTFE (3:15-25), said first 12' and second 12'' layers having a metallic support structure 11 (2:9-27) positioned there between and a third tubular layer 13 formed of a woven (3:19) textile material (4:46-54) disposed around the first 12' and second layers 12''. The support structure may be formed of monofilaments (3:1-7). The third textile layer 13 is adhered to the outer layer 12'' by adhesives (4:46-48). Planck discloses the claimed multilayer implantable prosthesis however fails to disclose the bonding agent, the application of the graft comprising a plurality of

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longitudinally spaced crimps, or that the bonding agent is applied in a solution of dimethylacetamide

Banas teaches a stent with ePTFE layers 36 surrounding a stent component 38 wherein the layers are bonded together by a silicon bonding agent (4:41-51) to form a vascular graft with an abluminal supporting structure capable of being diametrically reduced to an intraluminal delivery profile and self-expanding *in vivo* to conform to the anatomical topography at the site of intraluminal implantation (1:60+). The ePTFE graft maybe helically wrapped with the polypropylene (7:38-67) clad stent to form the tubular prosthesis (abstract). With reference to Figures 13 and 14 the elongate tubular graft of Banas comprises a plurality of longitudinally spaced crimps 88. Banas further discloses the method of heating the prosthesis to bond the layers together into a monolithic unitary structure (8:15-53). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the multilayer structure as disclosed by Planck in order to incorporate the method of applying the graft providing crimps as taught by Banas in order to produce an implantable prosthesis that is capable of being reduced to a smaller size for delivery and self-expands upon implantation to conform to the patient's vasculature structure.

Planck as modified by Banas, as discussed above, discloses the implantable device as claimed. Planck as modified by Banas however fails to disclose that the bonding agent comprises a polycarbonate urethane and is applied in a solution of dimethylacetamide.

Pinchuk et al teaches coating stent grafts with a polycarbonate urethane bonding agent for the purpose of enhancing hoop strength and connectivity, and applying the bonding agent in the form of a solution comprising dimethylacetamide to accelerate the drying time or spray buildup for polyurethane. Therefore in view of the teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the implantable stent graft disclosed by Planck and modified by Banas by incorporating a polycarbonate urethane bonding solution of dimethylacetamide as taught by Pinchuk in order to speed up the polymerization of the polyurethane.

Response to Arguments

Applicant's arguments filed 6/13/06 have been fully considered but they are not persuasive. The applicant argues that Planck does not teach 2 distinct layers, but this is simply not true they are described and shown as separate upper and lower layers. Therefore Planck clearly discloses distinct layers.

The applicant further discloses that the combination of Planck and Banas is not proper because the adhesive is used for different materials that are not specifically recited in Banas. However the novel feature of Banas is the helically supported graft not the bonding agent. Whether or not the bonding agent will bond to different materials is an established characteristic of the bonding agent. Banas simply teaches that it may be used to bond components of a stent graft that will be implanted into a person. Therefore the combination is believed to be proper and made final.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

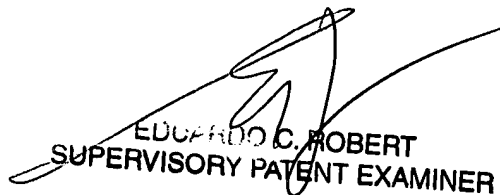
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
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CDP


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER